IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

PAMELA BUTLER, et al.,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	No. 4:18-CV-01701-AGF
	)	Lead Case
MALLINCKRODT LLC, et al.,	)	
	)	
Defendants.	)	
	)	

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

INTRODUCTION

Dr. Hu's opinions are admissible because he relied on valid scientific methodology to form them and they will assist the jury in determining whether the Plaintiffs have satisfied their burden of proof. The valid scientific methodologies Dr. Hu relies on are peer-reviewed literature, epidemiological studies, the Bradford Hill criteria, and a differential etiology. The Eighth Circuit holds all of these methods are generally accepted in the scientific community, meaning that any one of them standing on its own is sufficient to permit Dr. Hu to testify. The issues Defendants take with the conclusions Dr. Hu reaches by applying the facts and evidence to these methodologies is a matter for cross examination, not exclusion.

Dr. Hu's opinions will assist the trier of fact in determining whether the Plaintiffs have satisfied the elements necessary to prevail under Missouri law. Specifically, Plaintiffs must prove four elements: 1) they were exposed to a level of radiation significant enough to trigger their cancer; 2) they have cancer; 3) their cancer is consistent with their exposure; and 4) Defendants are responsible for their exposure. Dr. Hu compares the evidence of Plaintiffs' exposures with the peer-reviewed literature, epidemiological studies, Bradford Hill criteria, and the generally accepted model that even low levels of radiation cause cancer. Based on this, he concludes each Plaintiff meets the first element—he or she was exposed to enough radiation to activate their cancer. He then confirms the Plaintiffs' diagnosis, satisfying the second element. Finally, he conducts a differential epidemiology to conclude each Plaintiff's cancer is consistent with their exposure and there is no alternative independent cause, satisfying the third and fourth elements.

Dr. Hu's testimony is scientifically reliable and consistent with Missouri toxic tort law. If it is to be disbelieved, only a jury can do so. Dr. Hu's opinions should not be excluded.

LEGAL AUTHORITY

I. Because only a jury can weigh the competing opinions of experts, courts are required to liberally admit all but the most fundamentally unsupported opinions.

The Eight Circuit repeatedly emphasizes courts must liberally allow expert testimony and exercise their gate-keeping function to exclude only those opinions that are fundamentally unsupported by any scientific methodology. "While we adhere to this discretionary standard for review of the district court's Rule 702 gatekeeping decision, cases are legion that, correctly, under *Daubert*, call for the liberal admission of expert testimony … district courts are admonished not to weigh or assess the correctness of competing expert opinions." *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 562 (8th Cir. 2014).

Attacks directed at the factual basis for expert opinion generally give rise to issues of credibility, not admissibility. *Tussey v. ABB, Inc*., 746 F.3d 327, 337 (8th Cir. 2014) (additional citations omitted). "Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded." *Osment Models, Inc. v. Mike's Train House, Inc.,* 2010 WL 4721223, at *2 quoting *Wash Solutions, Inc. v. PDQ Mfg., Inc*., 395 F.3d 888, 895 (8th Cir. 2005) (additional citations omitted). Credibility issues are properly addressed through cross-examination by the opposing party. *Id.*

II. The Eighth Circuit recognizes differential etiology as a reliable, scientifically valid method and opinions based on them are "presumptively admissible."

The Eighth Circuit holds a differential etiology is a valid scientific method such that expert opinions based on differential etiology are admissible. A differential etiology is similar to a differential diagnosis, but while a differential diagnosis is used to determine what disease is causing a patient's symptoms, a differential etiology determines the cause of a disease. *See, Johnson v. Mead Johnson & Co., LLC,* 754 F.3d 557, 560 n.2 (8th Cir. 2014). An epidemiologist

performs a differential etiology by first identifying potential causes of the disease and then determining which cause or causes combined to trigger the disease. *Id.*

Causation opinions based on a differential etiology are "presumptively admissible" and cannot be excluded unless the plaintiff's diagnosis is "scientifically invalid." *Id.* (citing *Glastetter v. Novartis Pharm. Corp.,* 252 F.3d 986, 989 (8th Cir.2001) (per curiam) and *Turner v. Iowa Fire Equip. Co.,* 229 F.3d 1202, 1208 (8th Cir.2000)). The Eighth Circuit does not require an expert to rule out every potential alternative cause when performing a differential etiology. "[W]e have consistently ruled that experts are not required to rule out all possible causes when performing the differential etiology analysis." *Kirk v. Schaeffler Grp. USA, Inc*., 887 F.3d 376, 392 (8th Cir. 2018) (citing *Johnson,* 754 F.3d at 563). "Instead, such considerations go to the weight to be given the testimony by the factfinder, not its admissibility." *Johnson,* 754 F.3d at 564.

III. Dr. Hu is not limited to considering only the exposure evidence that can be mathematically calculated.

Neither the Eighth Circuit nor Missouri limits the exposure evidence an expert can consider to only what can be mathematically computed. To the contrary, a plaintiff does "not need to produce a mathematically precise table equating levels of exposure with levels of harm in order to show that she was exposed to a toxic level of [the chemical at issue]." *Bonner v. ISP Technologies, Inc*., 259 F.3d 924, 928 (8th Cir. 2001).

In *Bonner,* the expert "was unable to offer a threshold exposure amount for injury to occur [and] failed to determine how much FoamFlush Bonner was exposed to." *Bonner*, 259 F.3d at 932. His causation opinion nonetheless satisfied *Daubert* and supported an admissible case. He explained that exposures "as small as a quarter of a teaspoon can have toxic effects, and that inhalation is a more potent exposure mechanism than is ingestion." *Id.* This testimony was reliable

"evidence from which a reasonable person could conclude that the exposure probably caused her injuries." *Id.*

More recently, the Eighth Circuit again confirmed evidence of exposures beyond mathematical calculations satisfies both *Daubert* and plaintiff's burden for causation. *Kirk*, 887 F.3d 376 (2018). In *Kirk,* the plaintiff alleged she contracted autoimmune hepatitis (AIH) from exposure to defendant's TCE. *Kirk,* 887 F.3d at 381-82. Defendants sought to exclude plaintiff's experts on the grounds that they could not calculate the amount of TCE she was exposed to. *Id.* at 391. The court denied these motions and explained such calculations are not necessary because plaintiff's medical expert was free to rely on all evidence tending to show exposure at levels that, combining with other risk factors, caused the disease:

> While Dr. Gilbert's report does not estimate an exact level of exposure, it explains why such an estimate is not possible. It also provides a reliable basis for her opinion that [Kirk's] exposure to TCE was such that, over time, acting on a genetic predisposition, it caused [Kirk] to develop AIH, and it was not idiopathic [i.e., of unknown cause].

Id. The jury agreed with Dr. Gilbert and found defendants "had directly caused or contributed to Kirk's injury." *Id.* at 382. On appeal, the Eighth Circuit upheld the judgment, explaining:

> Dr. Everett testified to extensive TCE contamination in the Silver Creek community and the many ways Kirk was exposed to that contamination for many years. We do not require a mathematically precise table equating levels of exposure with levels of harm. Like the district court, we conclude Kirk submitted sufficient evidence of general causation to submit her claim to the jury.

Id., at 390-91 (internal citations omitted).

Here, as in *Kirk,* nothing prevents Dr. Hu from considering the substantial amount of Plaintiffs' exposure that cannot be mathematically calculated. Doing so is reliable and admissible under *Daubert* and Eighth Circuit precedence.

IV. **In Missouri, a plaintiff proves causation by showing exposure sufficient enough to cause her disease; that she has the disease; that her disease is consistent with her exposure; and that Defendants caused the exposure.**

In Missouri, a plaintiff proves causation in a toxic tort case by presenting evidence of enough exposure to cause or activate the disease along with expert testimony that the disease manifested itself in a way consistent with the plaintiff's exposure: "In a toxic tort case, the plaintiff's burden includes proof of 'an exposure to an identified harmful substance significant enough to activate disease[,] ... expert opinion that the disease found in plaintiff is consistent with exposure to the harmful substance[, and proof that] defendant was responsible for the etiologic agent of the disease diagnosed in plaintiff.'" *Kirk v. Schaeffler Grp. USA, Inc.,* 887 F.3d 376, 390 (8th Cir. 2018) (citing *Elam v. Alcolac, Inc.,* 765 S.W.2d 42, 173 (Mo. App. 1988)).

Missouri courts have never required plaintiffs to produce statistical modeling or mathematical formulas to prove the "significant enough to activate disease" element. Nor is there any requirement that a plaintiff's exposure must out-pace background exposure before it can be deemed "significant enough." Rather, each element of causation is examined as it specifically relates to the plaintiff and the substance at issue: Was she exposed to enough of the substance to activate the disease? If so, did she develop the disease, and did she do so in a manner consistent with her exposure? If so, is the defendant responsible for her exposure? Based on an affirmative answer to these three questions, a reasonable jury can find causation.

QUALIFICATIONS

I. **Dr. Hu is exceedingly qualified to offer his opinions; he holds multiple degrees from Harvard, has specific training on radiation's relationship to cancer, and has led award-winning research teams on the topic.**

Dr. Hu is a board-certified physician, he holds three degrees from Harvard in public health and epidemiology, and continued to study and publish on the relationship between cancer and

radiation exposure in the years since. After graduating from Brown University in 1976, Dr. Hu studied medicine at Albert Einstein College of Medicine while at the same time pursuing his Master in Public Health degree at Harvard. Exhibit A, C.V. of Howard Hu, M.D, M.P.H., Sc.D. at 2. He successfully completed both programs and then continued his course work at Harvard School of Public Health, earning his Masters in Public Health in 1986 and his Doctor of Science in Public Health in 1990, both in epidemiology. *Id.* He is board certified in internal medicine and also in preventative medicine (occupational medicine). *Id.* He has served as an instructor in medicine at Harvard Medical School, as an associate clinical and research physician at Brigham's & Women's Hospital, and as an assistant professor of occupational medicine at Harvard School of Public Health. *Id.* He has served as a professor at the University of Michigan's Schools of Public Health and Medicine, as an affiliate professor at the University of Washington's School of Public Health, and currently is the Flora L. Thornton Chair of the Department of Preventive Medicine, Keck School of Medicine, at the University of Southern California.

He also possesses expertise and experience specific to radiation and cancer. He trained specifically in radiobiology, radiological protection, radiation epidemiology and cancer epidemiology as part of his Masters in Public Health coursework in occupational health and Doctorate in Science coursework in epidemiology, all at the Harvard School of Public Health. Exhibit B, Expert Report of Dr. Hu for Pamela Butler, at 2.[1] He served as Chair of the Research Commission for the International Physicians for the Prevention of Nuclear War, in which role he and his co-authors conducted research and published articles and books on radiation, on the radiological and non-radiological hazards related to the production of plutonium, and on the general nuclear weapons industry. *Id.* He collaborated on environmental and molecular

[1] See also Exhibit C, Expert Report for Anthony Hines, p. 2; Exhibit D, Expert Report for Kenneth Koterba, p. 2; and Exhibit E, Expert Report for Emery Walick, p. 2.

epidemiologic studies of cancer as they relate, for example, to environmental risk factors for bladder cancer, lung cancer, prostate cancer, and genetic susceptibility factors related to B-cell lymphomas. *Id.* He also served on the Advisory Board for the Cancer Epidemiology Education in Special Populations Program at the University of Michigan School of Public Health. *Id.* He has lectured on translational research opportunities and challenges for cancer research, and has been serving for the past several years as the Principal Investigator of an investigation of cancer and the environment funded by Health Canada. *Id.*

Dr. Hu has the training, education, experience, and expertise to offer his opinions that exposure to the radioactive material in and around Coldwater Creek caused Plaintiffs' cancers.

BASES FOR SPECIFIC CAUSATION OPINIONS

I. Dr. Hu examines each Plaintiffs' exposure from Defendants' operations and materials, compares it to the scientific literature and risk assessments, and concludes they were exposed to an amount significant enough to activate their cancer.

For each Plaintiff, Dr. Hu uses the Bradford Hill Criteria to conclude the radiation from SLAPS and Latty Avenue can cause each Plaintiff's specific type of cancer. Defendants do not challenge these "general causation" opinions. Dr. Hu also hold specific causation opinions for each Plaintiff. To reach these opinions, he begins by studying the amount of radiation each Plaintiff was exposed to so that he can determine whether or not this amount is sufficient to activate the disease process. He devotes a section in his reports to exposure assessment, including his general review of the June 18, 2018 ATSDR Draft Report entitled "Evaluation of Community Exposures Related to Coldwater Creek St Louis Airport/Hazelwood Interim Storage Site (HISS)/Futura Coatings NPL Site, North St Louis County, Missouri." Ex. B, pp. 4-6. He also provides specific exposure numbers from Dr. Clark's expert report for each individual Plaintiff, as well as the evidence of additional exposures beyond this amount. *Id.*

For instance, he discusses how Dr. Clark's calculations do not represent Ms. Butler's true exposure: "these dose estimates are likely to be underestimates, given that they do not take into account Ms. Butler's dog and the known additional exposures associated with environmental contaminants adsorbing onto a dog's fur and dogs then transporting such contaminants into homes." *Id.,* at 12. Dr. Hu also relies on a report from the Missouri Department of Health that proves a statistically significant increase in breast cancer in area codes 63042 and 63134, where a significant amount of Ms. Butler's exposure occurred. *Id.*, at 13 (citing Yun S, Schmaltz CL, Gwanfogbe P, Homan S, Wilson J. Analysis of cancer incidence data in eight ZIP code areas around Coldwater Creek, 1996-201 1. Missouri Department of Health and Senior Services, September 2014).

After the Plaintiffs were deposed,[2] Dr. Hu supplemented his reports. Exhibits F, G, H and I. In his supplemental reports, Dr. Hu discusses the full range of exposures Dr. Clark is able to calculate for the Plaintiffs, including the maximum exposures. *Id.* Based on Dr. Clark's report, each Plaintiff's specific exposure history, including exposure that cannot be quantified by Dr. Clark, and the ATSDR's estimates for exposure, Dr. Hu explains that each Plaintiff's likely exposures were towards the higher end of Dr. Clark's range, i.e. approaching the "maximum." *Id.* Dr. Clark confirms that his numbers underestimate Plaintiffs' exposures in his deposition, which Dr. Hu reviewed. Exhibit J, Deposition of Dr. Hu in *Butler,* 269:11-15.

Dr. Hu also cites to the literature showing that the evidence and research "continues to favor" the generally accepted scientific theory regarding radiation's ability to cause cancer, known as the linear no-threshold model. This accepted model holds that even very small doses of radiation can cause cancer. Ex. H, pp. 3-4 (citing NAS (National Academy of Sciences). 2006. Health Risks

[2] Plaintiffs produced Dr. Hu's initial report shortly after filing their case, on April 1, 2019, in compliance with Case Management Order No. 14 (ECF 741) and the Court's January 25, 2019 Order (ECF 765).

from Exposure to Low Levels of Ionizing Radiation. BEIR VII Phase 2. Washington, DC: National Academy Press; and U.S. EPA, *Residual Risk—Report to Congress.* US Environmental Protection Agency, Office of Air and Radiation; Office of Air Quality Planning Standards. Research Triangle Park: March 199. EOA-453/R-99-001).

Finally, based on the evidence of exposure, the World Health Organization's risk assessments, the Environmental Protection Agency's protection standards, and the generally accepted causation models concerning cancer and radiation in the scientific community, Dr. Hu concludes each Plaintiff's exposure is significant enough to activate the disease process. *Id.,* at 3 (citing WHO. Communicating Radiation Risks in Paediatric Imaging. Geneva: World Health Organization 2016. ISBN 978 924 4 151034 9; and US EPA. Residual Risk, Supra). These opinions will assist a jury in determining whether Plaintiffs have established the first element of causation—that they have been exposed to radiation from Defendants in an amount "significant enough to activate disease." *Kirk*, 887 F.3d, 390 (quoting *Elam*, 765 S.W.2d, 173). They are based on reliable methodology, are relevant to the issues, and therefore admissible.

II. Dr. Hu compares the facts and circumstances of exposure with the development of disease to form his opinions that Plaintiffs' cancers are consistent with their exposure.

Dr. Hu dedicates a section of his reports to "Medical Assessments, Relevant Diagnosis, Family History." Ex. B, pp. 3-4. In this section, Dr. Hu summarizes his review of the medical records, including the relevant health history, diagnosis of injury, and the presence or absence of any risk factors. *Id.* He also considers the latency period for each disease the Plaintiffs are claiming. Ex. J, 143:23-144:1. And he looks at the unique characteristics of each Plaintiffs' exposure. For example, in discussing Mr. Koterba's, Mr. Walick's, and Mr. Hines' exposures, one of the factors he relies on to support his opinion that their disease is consistent with their exposure is that all of these Plaintiffs were exposed during childhood. *E.g.*, Ex. D, at 11 ("the exposures occurred during

childhood (birth to 9 years of age), which is known to be an age at which individuals are more susceptible to carcinogenic exposures") (citing Barton HA, Cogliano VJ, Flowers L, Valcovic L, Setzer RW, Woodruff TJ. Assessing susceptibility from early-life exposure to carcinogens. Environ Health Perspect. 2005 Sep;113(9):1125-33). In his supplemental reports, he discusses the Plaintiffs' depositions and confirms they support his opinions on causation, including that the development of each Plaintiffs' disease is consistent with their exposure. *E.g.*, Ex. I, p. 4 (the exposure at issue "more likely than not caused or contributed toward the development of Mr. Koterba's brain tumor.")

Dr. Hu's opinions regarding the age and duration of exposure, compared to the onset of disease, and considering the latency period, are reliable "expert opinion[s] that the disease found in plaintiff is consistent with exposure to the harmful substance." *Kirk*, 887 F.3d, 390 (quoting *Elam*, 765 S.W.2d, 173). Because these opinions are based on reliable methodology and will help the jury to decide the second element of Plaintiffs' exposure claims, they are admissible.

III. Dr. Hu conducted a differential etiology for each Plaintiff to support his specific causation opinions.

Having established that each Plaintiff was exposed to enough radiation to cause their cancer, and having established their cancers presented in a manner consistent with that exposure, Dr. Hu conducts a differential etiology by considering and ruling out other alternative independent causes. Not only does he review their medical records, and later their depositions, to identify any risk factors for their particular cancer, but he also requires each Plaintiff to complete a Family History Questionnaire. Ex. B, p. 3. Dr. Hu obtained this questionnaire from a genetic epidemiologist, well experienced in cancer research. It is designed to reveal any genetic risk factors for each Plaintiff.

Dr. Hu completes his differential etiologies by considering each risk factor and ruling them out as an alternative independent cause. For example, Mr. Walick's questionnaire revealed a cousin with brain cancer. Dr. Hu considers this and then, based on the fact that there is no history of brain cancer or any other genetic disorder associated with a higher risk for medulloblastoma in his more immediate family, rules it out as an independent genetic cause. Ex. E, p. 11 (Citing Northcott PA, Robinson GW, Kratz CP, Mabbolt DJ, Pomeroy SL, Clifford SC, Rutkowski S, Ellison DW, Malkin D, Taylor MD, Gajjar A, Pfistcr SM. Medulloblastoma. Nat Rev Dis Primers. 2019 Feb 14;5(1):1 1. doi: 10.1038/s41 572-0 19-0063-6. Review. PubMed PMID; 30765705.)

Based on his differential etiologies for each Plaintiff, Dr. Hu reaches his ultimate specific causation opinions. These opinions are based on a reliable methodology and will assist the jury in determining whether or not Defendants "directly caused or contributed to [Plaintiff's] injury." *Kirk*, at 382, *see also* MAI 19.01 (jury to find for plaintiff if it believes defendant "directly caused or directly contributed to cause damage to plaintiff.") Dr. Hu's causation opinions are based on reliable, accepted methodology and assists the jury in determining causation. They are admissible.

ARGUMENT

I. Defendants' critiques of Dr. Hu's opinions are without legal merit; to the extent they have any relevance, they touch on the weight of his opinions, not admissibility.

Defendants' criticisms of Dr. Hu's opinions are mostly based on a misunderstanding of the law and are therefore irrelevant, unduly prejudicial, and themselves inadmissible. Any merit or relevance they do have goes to the weight of Dr. Hu's opinions, not their admissibility. Defendants insist Dr. Hu must independently verify Dr. Clark's exposure opinions before he can rely on them. This is not the law; an expert is allowed to rely on the admissible opinions of another expert. Defendants claim Dr. Clark's opinions are inadmissible because he assumed each Plaintiff was

exposed to 70 years' worth of radiation. He did not; he calculated doses only for the years of exposure. Defendants argue the doses Dr. Clark is able to calculate are not relevant in a Price Anderson Act ("PAA") claim as a matter of law. But there is no national causation standard for a PAA claim; each case is governed by the substantive laws of the state where the claim arose. And in Missouri, all evidence of exposure, including both what can and what cannot be quantified, is relevant and admissible. Defendants' focus on a lack of epidemiological studies also ignores Missouri and Eighth Circuit law. Such studies are not a requirement, particularly here, where Dr. Hu explains why there are no such studies and confirms that even in their absence the "linear no-threshold" model of radiation's ability to cause cancer is favored by the scientific community. Defendants wrongly claim Dr. Hu failed to rule out certain possible alternative causes. The record shows he did. But even if he had not, an expert employing a differential etiology is not required to rule out all other causes, any failure to do so is grounds for cross-examination, not exclusion. Finally, they attack his qualifications, falsely claiming his only experience is "having taken two single-semester courses forty years ago." His C.V. easily disproves this. His opinions are admissible.

II. Dr. Hu can rely on the reports from Dr. Clark and the ATSDR.

Defendants' accusation that Dr. Clark assumed 70 years of exposure is false—he reconstructed doses only for the years of exposure. To annualize what those doses would be, Dr. Clark used the ATSDR's approach, which quantified a 70-year dose coefficient factor (DCF) for each radioisotope. Dr. Clark used this factor to determine what dose a Plaintiff received from the exposure for each year he or she was exposed, not to determine what dose a Plaintiff would receive over a 70-year period. For example, in Dr. Clark's dose reconstruction for Mr. Walick, his exposures were calculated from 1990 through 2008 (18 years), consistent with Mr. Walick's

presence at locations where radionuclide contamination was present. (Exhibit O, Dr. Clark Report for Emery Walick, p. 34). Dr. Clark presented in clear tables the Plaintiffs' cumulative doses and the health risk by organ (potential to develop cancer following exposure to the radioactive materials released by the defendants), specific to the duration of their individual exposures. *Id., See also* Exhibit P, Dr. Clark Report for Pamela Butler, P. 35 (Calculated dose based on 10 years of exposure); Exhibit Q, Dr. Clark Report for Anthony Hines, p. 35-36 (Calculated Effective Whole-Body Dose based on 18 years of exposure); and Exhibit R, Dr. Clark Report for Kenneth Koterba, p. 35, Calculated Effective Whole-Body Dose based on 52 years of exposure).

The ATSDR specifically rejected the same criticism Defendants make here. "ATSDR disagrees with the assertion that our use of the committed dose to age 70 resulted in gross overestimates of risk." Exhibit K. ATSDR's Public Health Assessment of the community exposure related to Cold Water Creek Report, at f-58. The ATSDR compared its formulas to other accepted exposure methods and found them to be accurate. "To test how ATSDR's method compared with the method suggested by the commenter, we used the AcuteDose code to estimate absorbed organ-specific doses . . . [w]e found that the doses to age 70 from the cumulative exposure were very close (within 10%) to our method." *Id.,* at f-59, *see also* f-11 ("ATSDR's simplified method gives cumulative dose estimates and lifetime cancer risks generally comparable with the more complicated approach. We concluded that our methodology would be a reasonable approximation for estimating lifetime risks."). Because the ATSDR verified the reliability of the method Dr. Clark uses, it cannot be the basis for disqualifying his opinions.

Defendants also attack Dr. Clark's report by insisting that because the ATSDR explained that the results of its community-wide assessment do not apply to any one individual, Dr. Clark's reliance on the methodologies used by the ATSDR renders his opinions unreliably inadmissible.

This argument ignores how Dr. Clark relies on ATSDR's methodologies. He is not simply taking the results and assuming they apply to Plaintiffs. Instead, he applies the formulas the ATSDR used to the circumstances of each Plaintiff's exposure. He does so by using data specific to Coldwater Creek and the Plaintiffs. The ATSDR cross-checked these formulas with the more complicated computer models of exposure and found them reliable. There is nothing improper or unscientific about Dr. Clark's reliance on them.

While Defendants selectively quote from ATSDR's report to imply ATSDR conceded its method is not accurate, the opposite is true. A full reading of the ATSDR's defense of the method it uses reveals the ATSDR confirmed that its method "simplifies the calculations and **allows clear presentation of the estimated dose and risk for each year an intake occurred**." Exhibit K, ATSDR ATSDR's Public Health Assessment of the community exposure related to Cold Water Creek Report, f-11 (emphasis added).

And because Dr. Clark's opinions are admissible, Dr. Hu is allowed to rely on them without first independently verifying them. "An expert may apply the results of another expert's calculations, if a proper foundation is laid … [a]ccordingly, Sommer may rely on McSwain's conclusions on engine vibrations and the pre-crash existence of a hole in fuel line no. 5." *Johnson v. Avco Corp*., 702 F. Supp. 2d 1093, 1103 (E.D. Mo. 2010) (citing *Dura Auto. Sys. of Ind., Inc. v. CTS Corp*., 285 F.3d 609, 613 (7th Cir.2002). Defendants' quote *In re TMI Litig*., 193 F.3d 613, 715 (3d Cir. 1999) in an attempt to convince the Court otherwise, but fail to tell the Court why the expert in that case needed to lay an independent foundation for the expert reports he was attempting to rely on: those reports were authored by 11 different experts, 10 of which the court had already struck as being unreliable. That is not the case here.

Finally, Defendants repeatedly and misleadingly quote Dr. Hu's "obvious errors" remark, without identifying the errors Dr. Hu was referring to. Dr. Hu never testified Dr. Clark's opinions or conclusion contained obvious errors. He was not admitting to relying on an obviously flawed analysis. He did not state Dr. Clark's calculations had errors. He simply meant that there were a few obvious typos, such as the wrong Plaintiff's name appearing in an introductory paragraph. It had nothing to do with the reliability of his methodology or results. Because Dr. Clark's opinions are admissible, Dr. Hu does not need to lay any further foundation to rely on them.

III. Because Plaintiffs' true exposures are on the high end of the range Dr. Clark was able to quantify, his maximum exposures are relevant.

Dr. Hu's consideration of Dr. Clark's maximum dose for each Plaintiff is consistent with standard practice in conducting a reliable exposure analysis. Defendants claim Dr. Clark's maximum calculations represent an impossible scenario because his dose reconstruction includes exposures from more than one location in a given day. Dr. Clark explained in his deposition that such a scenario is not impossible:

> Q. Okay. Isn't it true that the individual's exposure would not have occurred at one point in time or at one location?
>
> A. That is correct.
>
> Q. Okay. They move around; correct?
>
> A. They move around, yes.
>
> Q. And different areas that you've evaluated in your report had different concentrations of soil; correct?
>
> A. Correct.

(Exhibit L, Deposition of Dr. Clark, September 18, 2019, Pg. 249:9-18).

As there was nothing that restricted any Plaintiff from being exposed to radionuclides at several locations in any given day, it is more than reasonable for Dr. Clark to calculate their

potential dose based on concentrations levels at those locations, and for Dr. Hu to consider those doses in his analysis. This is particularly so given the other exposure pathways that cannot be quantified (*e. g.,* Ms. Butler's exposure from her dog's fur, Mr. Hine's exposure while breathing the Latty Avenue air, etc.). Dr. Clark even explains in his deposition that his numbers underestimate Plaintiffs' true exposures. Nothing requires Dr. Hu to ignore the unquantifiable evidence of exposure, as well as the "maximum" quantifiable evidence.

The EPA also disagrees with Defendants' characterization of this approach. The EPA uses "exposure descriptors" which are estimates for a specific point on the exposure distribution (e.g., mean, median, 95th percentile, maximum). (*See* Exhibit M, Exposure Assessment Tools by Approaches - Indirect Estimation (Scenario Evaluation) (2004). The EPA states that these high-end estimates of exposure, "**are generally considered to be more realistic or more likely to occur compared with bounding estimates**." *Id*. (emphasis added). The following descriptors all account for the individuals at the high end of the exposure distribution:

- **Reasonable maximum exposure** (RME) – the highest exposure reasonably likely to occur, generally assumed to be in the range of the 90th and 99.9th percentiles (U.S. EPA, 2001)
- **Reasonable worst-case exposure** – the lower part of the high-end exposure range, which is above the 90th percentile but below the 98th percentile (U.S. EPA, 1992)
- **Maximum exposure** – the range above the 98th percentile (U.S. EPA, 1992).

Id. (emphasis in original). The EPA endorses the use of these high-end estimates in determining possible exposure scenarios: "These high-end estimates are intended to assess exposures that are higher than average, but still within a realistic, reasonable anticipated range." *Id*.

This is precisely the approach Dr. Clark used in analyzing each Plaintiffs' exposures to radionuclides, which Dr. Hu then relied on. The maximum exposure is relevant for a jury to consider when determining whether Plaintiffs' exposures were enough to cause or contribute to

cause their respective injuries. As this method is derived from and endorsed by the EPA it is reliable and does not create an "unrealistic" exposure scenario as Defendants would have it. Particularly considering that both expert opined that the true amount of exposure is greater than what could be quantified, opinions the Eighth Circuit expressly permits. Dr. Hu's opinions regarding maximum exposure are accepted by the Eighth Circuit and the scientific community; they are admissible under *Daubert*.

IV. Dr. Hu considered the latency period.

Defendants accuse Dr. Hu of failing to consider the latency period when forming his opinions, but Dr. Hu testified in his deposition that he did consider latency:

> Q. Did you consider the latency period for any of the plaintiffs in coming to – in conducting your analysis?
>
> **A. Yes**.

Ex. J, 143:23-144:1.

Defendants ignore this testimony because they want to disagree with how Dr. Hu accounted for latency. According to Defendants, if a latency period is ten years, then this means a Plaintiff cannot have any exposure to radiation in the ten years leading up to his diagnosis: "The exposure period must therefore end ten years before diagnosis." Defendants' Brief, p. 10. As Dr. Hu explains, this is not correct. The latency period begins at the onset of exposure, and does not require the exposure period to end: "As we discussed before in terms of how we define latency, I define it as when the exposure of interest began and when the cancer was detected either by the patient or the clinician, and that would be 10 years." Ex. T, Depo. of Dr. Hu in *Strong*, Vol I, 169:21-25. Here, Plaintiffs' exposures of interest all began more than twenty years before their diagnoses—twice as long as the presumed ten-year latency period. Some of them began much, much earlier. And for three of the Plaintiffs, their earliest exposures occurred when they were young and at even

greater risk, given the susceptibility of children to radiation. (Ex. J, 142:21-25). Dr. Hu properly accounted for latency. At the most, Defendants' criticism is grounds for cross examination.

V. Because the "linear no threshold model" is generally accepted in the epidemiology community and has substantial support in the literature, Dr. Hu does not need to cite to epidemiological studies to render his causation opinions admissible.

While Defendants cite Third Circuit and Pennsylvania law, the Eighth Circuit does not require an expert cite to epidemiological studies before his causation opinions are admissible. "[T]here is no requirement that published epidemiological studies supporting an expert's opinion exist in order for the opinion to be admissible." *Bonner v. ISP Techs., Inc.,* 259 F.3d 924, 929 (8th Cir. 2001) (citing *National Bank of Commerce v. Associated Milk Prods. Inc.,* 191 F.3d 858, 862 (8th Cir.1999)). But even the Third Circuit case Defendants rely on does not hold what they say it does. *In re TMI Litig*., 193 F.3d 613, 715 (3d Cir. 1999). There, the Third Circuit acknowledged the scientific community's acceptance that even the lowest levels of radiation can cause cancer: "Even at very low doses it is possible that ionizing radiation may deposit sufficient energy into a cell to modify it … Consequently, it is assumed that there is no threshold for the initiation of a stochastic event." *In re TMI Litig.,* 193 F.3d 613, 642 (3d Cir. 1999) (citing Annals of the International Commission on Radiological Protection, ICRP Publication 60, 1990 Recommendations of the International Commission on Radiological Protection 94 (1990); and Fred A. Mettler, Jr., M.D., and Arthur C. Upton, M.D., Medical Effects of Ionizing Radiation 7 (2d ed.1995)).

In *TMI,* the Third Circuit reversed summary judgment as to certain plaintiffs claiming cancer. *Id.*, 726-27. The Third Circuit held it was an abuse of discretion for the district court to ignore this scientific evidence and substitute its own judgment for the minimum level of exposure necessary to realistically cause cancer:

> However, the fact that risks of cancer from exposure at low doses are based on extrapolations from higher doses does not mean that the scientific community believes that there is no causal connection between a low-level exposure and cancer induction. We do not believe that the scientific community views that connection to be speculative. Rather, as noted above, at very low doses it is possible that ionizing radiation may deposit sufficient energy into a cell to adversely modify it. ICRP, at 98. *Indeed, scientists assume that there is no threshold for the induction of cancer.* MEDICAL EFFECTS, at 69. *In other words, ionizing radiation can cause cancer even at the lowest doses, and therefore it has to be taken into account at all dose levels.* ICRP, at 67.

Id. (emphasis added).[3]

This opinion from the Third Circuit is on point and dispositive: Defendants are not entitled to prevent Dr. Hu from offering his opinion that, consistent with the generally accepted view of the scientific community, radiation can cause cancer even at the lowest doses. Because his opinion is based on reliable science, it is admissible.

And just as Defendants selectively quote the Third Circuit, so too do they selectively quote Dr. Hu. They ignore his deposition testimony explaining he basis for his opinions that Plaintiffs' doses were significant enough to cause their cancers:

> As I stated in my reports, in the opinion of the most recent report of the Biological Effects of Ionizing Radiation Committee, that's the BEIR VII report and the USEPA, current evidence, including recent research, continues to favor the linear no-threshold model of carcinogenesis, i.e., the probability of developing cancers is presumed to increase in a linear manner with incremental increases in radiation dose even at relatively low levels of exposure.

Ex. J, 134:19-135:4

Defendants also cite to Dr. Hu's testimony in *Strong* while ignoring the portions where he discusses his long history of expertise on the linear no-threshold model. In 1993, he co-authored a

[3] On remand, the district court held that because discovery was closed, the non-trial plaintiffs could not supplement their expert reports to include opinions based on the general acceptance within the scientific community that any dose of radiation can cause cancer. The district court's dismissal on these grounds is not applicable here.

book[4] that described what was at the time known as the linear no-threshold hypothesis. Ex. S, 168:15-24. As he explained, the scientific community no longer considers it to be just a hypothesis:

> **Q:** What has changed in the intervening years that led you to believe that is no longer a hypothesis?
>
> **A:** Well, there's been quite a bit of research done in the last 25 years since this book was published, and there's been studies that have looked at very large populations by pooling data, meta- analyses, *et cetera*, that still see a signal of cancer risk at very low doses of radiation, which has been interpreted as support for what is now termed the linear no-threshold model as opposed to a hypothesis.

Id., 169:7-18.

Similarly, Defendants ignore his testimony from *Czapla,* where he discusses his peer-review of studies that are relevant to the linear no limit threshold model. Ex. N, 113:18-114:5. And while Defendants complain there are no epidemiological studies to support this model, Dr. Hu explains the linear no threshold model is generally accepted by the epidemiology community:

> **Q:** (By Mr. Watson) Outside of the regulatory community, is it accepted in the epi community?
>
> **A:** I think there's some controversy here, but I think in general my colleagues in general are aligned with that theory.
>
> **Q:** Can you say to a reasonable degree of medical certainty that the linear no threshold theory is appropriate for low dose radiation without an epi study?
>
> **A:** Well, as far as I know, when the Biological Effects of Ionizing Radiation Committee considered the dose response relationship they were both looking at the epidemiologic literature as well as the experimental literature, so yeah, even discounting the epidemiology literature, I think there's -- there is substantial experimental literature supporting the linear no threshold model.

Id., 114:18-115:9.

The linear no threshold model is accepted in the scientific community and supported by substantial evidence. Dr. Hu's reliance on this generally accepted scientific model of radiation's

[4]And yet Defendants ask the Court to hold his radiation experience consists of only taking two courses.

ability to cause cancer, and the decades of research to support this as reflected by the reports of the National Academy of Sciences and the EPA, cannot be grounds to exclude his testimony.

VI. There is no "background plus background" relevance test; not in Missouri, not in the Eighth Circuit, not even in the *TMI* cases Defendants rely on.

As explained above, in Missouri and the Eighth Circuit, there is no "background plus background" test for causation. All a plaintiff must do is make a submissble case on causation is show they were exposed to enough of a substance to cause their disease, and that their disease is consistent with their exposure. To the extent the Pennsylvania cases Defendants rely on require a higher burden, they are not applicable here.

But even those cases do not require Plaintiffs to prove exposure to "background plus background" before they make a submissible case. *In re TMI Litig*., 193 F.3d 613 (3d Cir. 1999); *McMunn v. Babcock & Wilcox Power Generation Group, Inc*., 131 F. Supp. 3d 352 (W.D. Penn. 2015). Instead, a plaintiff must simply show they were exposed to defendants' radiation in addition to their background exposures, thus putting their total exposure above background levels.

Both *TMI* and *McMunn* rely on *In re Paoli Railroad Yard PCB Litigation*, 916 F.2d 829 (3d Cir.1990). In *Paoli,* the Third Circuit reversed summary judgment entered for defendants, holding Plaintiffs made a submissible case that they had been exposed to PCBs above background level. *Paoli*, 916 F.2d 861. There, the evidence of background took the form of parts per billion (ppb) of PCBs as measured in the bloodstream. *Id.* While defendants claimed natural background was 40 ppb, plaintiffs claimed it was below 3 ppb. *Id.* Plaintiffs claimed only 10% of the population has a natural background of 5ppb, and anything greater than that should be considered high. *Id.,* n.9. The district court adopted a natural background of 4.2 ppb to 6.4 ppb, levels which a number of plaintiffs were above. Based on this evidence, the Third Circuit held a "jury could believe plaintiffs' evidence regarding normal PCB background levels and from there could conclude that

these plaintiffs were exposed to a *larger than average dose* of PCBs." *Id.,* at 862. There was no requirement that the plaintiffs' total exposure be twice the average dose, only that they were exposed in total to a larger than average dose—exactly what Plaintiffs present evidence of here.

McMunn confirms this is the standard, holding that the plaintiffs there needed to show they were exposed, on top of natural background, to the specific uranium from defendant's operation. That court explained that the holding in *TMI* does not require a plaintiff to prove exposure to a threshold level of radiation, "but that they were exposed to the radiation that they claim caused their injuries. That is, in this case, Plaintiffs still must demonstrate that they were exposed to 'this radiation,' that is, inhaled uranium from the Apollo plant in excess of normal background radiation amounts[5]. Otherwise, they cannot demonstrate causation." *McMunn,* 131 F. Supp. 3d 552. Because plaintiffs' experts had made no attempt to estimate their dose, plaintiffs had no evidence that they were exposed to the inhaled uranium from the Apollo plant in any dose, and therefore could not make a submissible case. Here, of course, Plaintiffs present ample evidence of the doses they were exposed to from Defendants' radiation which pushed their total exposure above background.

But even if they had not, Plaintiffs are proceeding under Missouri law, which provides they do so by showing they were exposed to radiation in an amount significant enough to activate their disease, and that their disease is consistent with their exposure. There is no "background plus background" requirement[6]. Dr. Hu's opinions track this standard, and are admissible.

VII. Even though he did so, Dr. Hu is not required to rule out all other potential causes of cancer before Plaintiffs are entitled to have a jury consider the opinions he formed based on his differential etiologies.

[5] Again, as is clear from *Paoli* "in excess of normal background" does not mean background plus background, it simply means exposure to defendant's radiation resulted in an overall exposure that exceeded background levels.
[6] Even if there were, Dr. Clark explains that in terms of "this radiation," that is, the radioisotopes from SLAPS and Latty Avenue, Plaintiffs were exposed to those isotopes at levels many times greater than the natural background level for those isotopes. Hence, Plaintiffs can prove "background plus background plus background plus background…" and therefore make a submissible case under and standard.

A differential etiology "is a tested methodology, has been subjected to peer review/publication, does not frequently lead to incorrect results, and is generally accepted in the medical community." *Turner v. Iowa Fire Equip*. Co., 229 F.3d 1202, 1208 (8th Cir. 2000) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262–63 (4th Cir.1999)). Dr. Hu confirms he uses a differential etiology, taking into account that cancers can often have other contributing causes:

> Q. As I understand it, what -- you attempted to perform a differential etiology analysis for these plaintiffs; is that fair?
> A. More or less, yes.
>
> Q. All right. That essentially means that you try and rule in potential causes or risk factors for a specific disease, and then systematically rule them out until you get to the one that you think caused it?
>
> A. No. I mean, I'm trying to weigh the potential influence of different factors without attempting to ascribe causation to any single one factor, with the possible exception of finding a particular factor, like an overwhelming genetic factor that would be a dominant risk factor.

Ex. J, 216:24-217:13.

Dr. Hu explained differential etiology is a valid method for all diseases, even those with multiple causes, whether they be known or unknown, such as the cancers in this case:

> Q. Does that methodology work in a disease such as cancer where it is believed to have many unknown causes?
>
> A. It works as well as it does for just about most other diseases.

Id., 84:2-6.

Defendants ask the Court to ignore this testimony, Dr. Hu's differential etiology, and Eighth Circuit case law in order to exclude Dr. Hu's opinions because Defendants believe Dr. Hu failed to sufficiently rule out other causes of Plaintiffs' cancers. Dr. Hu, though, specifically considered all other potential risk factors for each Plaintiffs' cancer and explained why he did not believe any of them represented an independent cause.

Even if he had not, his opinions are still admissible. The Eighth Circuit holds an "expert's causation opinions should not be excluded because he or she has failed to rule out *every* possible alternative cause." *Lauzon v. Senco Products, Inc*., 270 F.3d 681, 693 (8th Cir.2001) (citing *Westberry v. Gilslaved Gummi AB*, 178 F.3d 257, 265 (4th Cir. 1999) (emphasis in original). In *Lauzon*, the court found the district court abused its discretion in excluding the plaintiff's expert's opinion even though there remained an alternative cause the expert could not rule out: "the doctor's explanations as to conclusions not ruled out went to the weight of the evidence." *Id.*, at 694. The court held that to hold otherwise denigrates Justice Blackmun's observation in Daubert:

> [I]n this regard respondent seems to us to be overly pessimistic about the capabilities of the jury and of the adversary system generally. Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.

Id. (citing *Daubert v. Merrell Dow Pharm., Inc*., 509 U.S. 579, 596 (1993).

Likewise, in *Bonner* the Eighth Circuit ruled it was proper to allow an expert to testify even though, among other things, he "failed to rule out other possible causes of her injury." *Bonner*, 259 F.3d at 932. Because "the scientific questions were best addressed by allowing each side to present its experts and then submitting their opinions to the jury." *Id.*

Plaintiffs are entitled to have Dr. Hu offer his specific causation opinions to the jury and explain the differential etiology he used to help support these opinions. To the extent he failed to rule-out all other potential causes to the satisfaction of Defendants those failures go to the weight of his opinions and can be explored on cross examination. They are not grounds for exclusion.

VIII. Dr. Hu's immense qualifications remain, notwithstanding Defendants' critiques.

It is not true that "Dr. Hu's experience with ionizing radiation (to say nothing of the ability of particular radionuclides to cause specific cancers in humans) is limited to his having taken two

single-semester courses forty years ago." Defendants Brief, p. 25. As discussed, he has conducted research, written books, and published articles on radiation and its dangers. He has peer reviewed such articles too. He has testified on this subject as well, including in two other cases involving much of the same nuclear waste at issue in this case. No Court has excluded his testimony. In fact, the Western District of Pennsylvania has explicitly deemed his opinions on radiation and cancer admissible. "The alleged flaws in Dr. Hu's methodology go to the weight of Dr. Hu's opinion, not its admissibility … because reasonable scientific minds can differ on the methodologies discussed, the motion to exclude the opinion of Dr. Hu will be denied." *McMunn v. Babcock & Wilcox Power Generation Grp., Inc*., No. 2:10CV143, 2014 WL 814878, at *9 (W.D. Pa. Feb. 27, 2014).

CONCLUSION

Defendants exaggerate the alleged flaws in Dr. Hu's credentials, just as they exaggerate the alleged flaws in his differential etiology, in the literature supporting his opinions, in the scientific community's acceptance of his methodologies, and in Dr. Clark's calculations. In truth, Dr. Hu has vast more experience than two courses, he did not fail to rule out independent alternative causes, the epidemiology community accepts the liner no threshold model, and Dr. Clark does not assume 70 years of exposure for each Plaintiff. Defendants overstate their arguments in the hopes that the Court will agree that any flaws in Dr. Hu's opinions raise to admissibility, not weight. But, as the court in *McMunn* rightly observed: "There is a difference between what is unreliable support and what a trier of fact may conclude is insufficient support for an expert's conclusion." *Id.* Perhaps a jury will disagree with Dr. Hu, perhaps not. But the choice properly lies with the jury. Defendants' motion to exclude Dr. Hu's testimony should be denied.

Respectfully Submitted,

HUMPHREY, FARRINGTON & McCLAIN, P.C.

/s/ Jonathan Soper
Kenneth B. McClain #32430
Jonathan M. Soper #61204
Colin W. McClain #64012
221 West Lexington, Suite 400
Independence, MO 64050
Telephone: (816) 836-5050
Facsimile: (816) 836-8966
kbm@hfmlegal.com
jms@hfmlegal.com
cwm@hfmlegal.com
ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that on the 29th day of September, 2021, I electronically filed the above with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to counsel of record.

/s/ Jonathan Soper
Attorney for Plaintiffs

SHOOK, HARDY & BACON LLP
David R. Erickson # 31532MO
Steven D. Soden # 41917MO
Anthony R. Martinez # 61791MO
2555 Grand Boulevard
Kansas City, MO 64108-2613
Phone: (816) 474-6550
Fax: (816) 421-5547
derickson@shb.com
ssoden@shb.com
amartinez@shb.com
ATTORNEYS FOR DEFENDANT MALLINCKRODT LLC

RILEY SAFER HOLMES & CANCILA, LLP
Brian O. Watson, #68678MO
70 W. Madison St., Ste. 2900
Chicago, Illinois 60602
Telephone: (312) 471-8700
Facsimile: (816) 836-8966
bwatson@rshc-law.com
ATTORNEY FOR DEFENDANT COTTER CORPORATION (N.S.L)